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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,383	11/25/2003	Marc Nasoff	021288-002920US	5854

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EXAMINER	
JOYCE, CATHERINE	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,383	NASOFF ET AL.	
	Examiner	Art Unit	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-64 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7, 8-20, 21-27, 29-43, 44-47, 49-60, 64 as drawn to a method of inducing apoptosis in a cancer cell comprising contacting cells with an anti-DR5 affinity agent agonist and an apoptosis-inducing agent, and to physiological compositions comprising a therapeutically effective amount of the agonist and the agent, classified in class 424, subclass 130.1.

II. Claims 1, 6, 7, 8-20, 21-23, 28, 29-43, 48, 49-60 as drawn to a method of inducing apoptosis in a cancer cell, comprising contacting cells with an anti-DR4 affinity agent agonist and an apoptosis-inducing agent, and to physiological compositions comprising a therapeutically effective amount of the agonist and the agent classified in class 424, subclass 130.1.

III. Claims 61-63 as drawn to an affinity agent with the binding specificity of an antibody and to cells that express the affinity agent, classified in class 530, subclass 387.1.

3. The inventions are distinct, each from the other, because of the following reasons:

The inventions of groups I and II are materially distinct methods and compositions that differ at least in method steps and reagents. For example, Group I is drawn to methods and compositions for inducing cancer cell apoptosis using an anti-DR5 affinity agonist , and Group II is drawn to methods and compositions for inducing cancer cell apoptosis using an anti-DR4 affinity agonist. Furthermore, each of the

groups employs structurally distinct reagents to accomplish the objectives via the interaction with different cellular targets. Searching the groups together would pose an undue search burden.

Group III inventions and Group I and II inventions are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the affinity agent of group III can be used in different methods such as affinity chromatography and ELISAs.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group I is further subject to election of a single disclosed species.

Claims 1, 21, and 43 are generic to a plurality of disclosed patentably distinct species comprising methods method of inducing apoptosis in a cancer cell comprising contacting cells with an anti-DR5 affinity agent agonist and an apoptosis-inducing agent, and to physiological compositions comprising a therapeutically effective amount of the agonist and the agent. The species are as follows: (a) the agent prevents or reduces expression of BCL-2 (claims 10, 32, 52); (b) the agent prevents activation of NFκB (claims 11, 33, 53); (c) the agent prevents degradation of IκB (claims 12, 34, 54); (d) the agent is a proteosome inhibitor (claims 13, 35, 55); (e) the agent is an inhibitor of an Inhibitor of Apoptosis (IAP) protein (claims 15, 37, 56); (f) the agent is an antagonist of PAK1 (claim 18, 40, 58); (g) the agent is an antagonist of nsurf (claims 19, 41, 59); (h) the agent is an antagonist of JIK (claims 19, 41, 59); (i) the agent is siRNA (claims 20, 42, 60); (j) the agent prevents or reduces expression of UbcH10 (claims 32, 41, 52, 59).

The methods are patentably distinct because they are directed to the use of structurally and functionally distinct apoptosis inducing agents.

6. Group II is further subject to election of a single disclosed species.

Claims 1, 21, and 43 are generic to a plurality of disclosed patentably distinct species comprising methods method of inducing apoptosis in a cancer cell comprising contacting cells with an anti-DR5 affinity agent agonist and an apoptosis-inducing agent, and to physiological compositions comprising a therapeutically effective amount of the agonist and the agent. The species are as follows: (a) the agent prevents or reduces expression of BCL-2 (claims 10, 32, 52); (b) the agent prevents activation of NFκB (claims 11, 33, 53); (c) the agent prevents degradation of IκB (claims 12, 34, 54); (d) the agent is a proteosome inhibitor (claims 13, 35, 55); (e) the agent is an inhibitor of an Inhibitor of Apoptosis (IAP) protein (claims 15, 37, 56); (f) the agent is an antagonist of PAK1 (claim 18, 40, 58); (g) the agent is an antagonist of nsurf (claims 19, 41, 59); (h) the agent is an antagonist of JIK (claims 19, 41, 59); (i) the agent is siRNA (claims 20, 42, 60); (j) the agent prevents or reduces expression of UbcH10 (claims 32, 41, 52, 59). The methods are patentably distinct because they are directed to the use of structurally and functionally distinct apoptosis inducing agents.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP. 809.02(a).

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 of the other invention.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine M. Joyce
Examiner
Art Unit 1642

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
1/3/05